510(k) Summary

DEC 21 2001

K013482

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 521-7637

Contact Person: Kerwin Kaufman

Date Prepared: October 18, 2001

2) Device name

Proprietary name: Abuscreen OnLine Opiates 300/2000

Common name: Opiates Test System

Classification name: Enzyme immunoassay, opiates

3) Predicate device

We claim substantial equivalence to the currently marketed Abuscreen OnLine II Opiates 300/2000 assay (K974840).

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4) Device Description

The Abuscreen OnLine Opiates 300/2000 assay is an in vitro diagnostic test for the qualitative and semi-quantitative detection of morphine and its metabolites in human urine on automated clinical chemistry analyzers at cutoff concentrations of 300 and 2000 ng/mL

Principal of procedure

The Abuscreen OnLine Opiates 300/2000 assay is based on the kinetic interaction of microparticles in a solution (KIMS) as measured by changes in light transmission. In the absence of sample drug, soluble drug-polymer conjugates bind to antibody-bound microparticles, causing the formation of particle aggregates.

When a urine sample containing the drug in question is present, this drug competes with the drug conjugate for microparticle-bound antibody. Antibody bound to sample drug is no longer available to promote particle aggregation, and subsequent particle lattice formation is inhibited.

As the aggregation reaction proceeds in the absence of sample drug, the absorbance increases. Conversely, the presence of sample drug diminishes the increasing absorbance in proportion to the concentration of drug in the sample. Sample drug content is determined relative to the value obtained for a known cutoff concentration of drug.

Negative Sample

drug-polymer conjugate + antibody-bound microparticle = particle aggregates
(↑ absorbance)

Positive Sample

sample drug + antibody-bound microparticle = particle aggregation inhibited
drug-polymer conjugate + antibody bound microparticle = particle aggregates

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5.) Intended Use

The Abuscreen OnLine Opiates 300/2000 assay is an in vitro diagnostic test for the qualitative and semi-quantitative detection of morphine and its metabolites in human urine on automated clinical chemistry analyzers at cutoff concentrations of 300 and 2000 ng/mL. Semi-quantitative test results may be obtained that permit laboratories to assess assay performance as part of a quality control program.

6.) Comparison to the Predicate Device

The Roche Abuscreen OnLine Opiates 300/2000 assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Roche Abuscreen OnLine II Opiates 300/2000 (K974840).

The Abuscreen OnLine Opiates 300/2000 assay utilizes the *same reagent formulation* as the currently marketed Abuscreen OnLine II Opiates 300/2000 assay (K974840). Differences between this application and the cleared assay include:

- addition of a 300 ng/mL semi-quantitative cutoff claim, and
- application to the Hitachi 900 series and Modular series of analyzers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 21 2001

Mr. Kerwin Kaufman
Regulatory Affairs Consultant
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: k013482
Trade/Device Name: Roche Diagnostics Abuscreen OnLine Opiates 300/2000
Regulation Number: 21 CFR 862.3650
Regulation Name: Lead test system
Regulatory Class: Class II
Product Code: DJG
Dated: October 18, 2001
Received: October 19, 2001

Dear Mr. Kaufman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K013482

Device Name: Roche Diagnostics Abuscreen OnLine Opiates 300/2000

Indications for Use: An in vitro diagnostic test for the qualitative and semi-quantitative detection of morphine and its metabolites in human urine on automated clinical chemistry analyzers at cutoff concentrations of 300 and 2000 ng/mL. Semi-quantitative test results may be obtained that permit laboratories to assess assay performance as part of a quality control program.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013482